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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,183	01/26/1999	NORDINE CHEIKH	16517.228	9529

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/237,183	CHEIKH ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 7-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 7-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 10 November 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claims 1 and 3-6 are cancelled. Claims 2 and 7-27 are hereby examined.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 7-27 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the Final Office action mailed 24 February 2005.

Response to Applicant's Arguments

1. Applicant argues that the disclosed nucleic acid molecules provide at least one specific benefit to the public, for example, use to encode a sucrose pathway enzyme or fragment thereof.

This is not persuasive, as use to encode a sucrose enzyme or fragment thereof supports the requirement for further research in order to establish a patentable utility since such a use is clearly a research project without defining any specific or substantial utility for any sucrose pathway genes that may be identified. Additionally, the specification lacks specific procedures for performing the use and thus also failing to provide a utility in currently available form.

2. Applicant further argues that "the claimed nucleic acid molecules provide identifiable benefits, for example, use to encode triose phosphate, fructose 1,6-biphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, frustokinase, NDP-kinase, or UDP-glucose pyrophosphorylase as nucleic acids markers and probes; to identify and obtain nucleic acid homologues; in microarray as gene specific targets; to identify the presence or absence of a polymorphism; use to transform plants; to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule; and use to overexpress or suppress a desired protein".

This is not persuasive. The claims do not have a specific asserted utility because the disclosed uses of these compositions are not specific to the claimed nucleic acids and are generally applicable to any nucleic acid. The research contemplated by applicant(s) to discover genes does not constitute a specific and substantial utility. Potential uses for nucleic acid homologue identification, for example, do not provide an immediate benefit. Similarly, the other

listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic acids.

3. Applicant argues that "one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to encode triose phosphate, fructose 1,6-biphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, frustokinase, NDP-kinase, or UDP-glucose pyrophosphorylase or fragments thereof". Applicant states that the specification provides evidence based upon sequence identity that the claimed nucleic acid molecules encode a polypeptide having at least 80% identity to known plant sucrose enzymes".

This is not persuasive, as stated previously. Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Furthermore, it is unclear whether the similar sequence identified in the prior art has actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no

effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); and Russell et al. (Journal of Molecular Biology, 244:332-350, 1994) (all cited previously). However, this level of factual evidence is absent here.

4. Applicant argues that another utility disclosed in the specification is "use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism". Applicant argues that "a microscope or screening assay can be used for learning about products or processes".

This is not persuasive. A microscope, for example, is useful for determining structure of *any* sample of interest at the macroscopic, microscopic or molecular level, depending on the type of microscope. It is a generally useful tool for a wide range of specific uses. One does not usually use a microscope to study related microscopes. Further, a microscope has a specific and substantial utility of magnifying images to allow the visualization of items too small to be seen by the unaided eye. This utility is specific for a microscope and is based on the physical structure of the lenses and mirrors present within the microscope. Applicants are effectively arguing that a nucleic acid and microscope are analogous because they can be used as a research tool. However, the claimed nucleic acid can only be used to detect sequences that themselves have no specific and substantial utility. This is analogous to the disclosure of a microscope containing a slide which contains an unknown smear of matter and providing claims to the unknown smear of

matter. In regard to the disclosed sequence, it is a fragment of larger sequence that has no described function that would allow one to identify a specific plant protein product as recited by the claims. With respect to the detection of polymorphisms being a specific and substantial utility, the argument is not convincing because the detection of a polymorphism is not useful until the polymorphism is associated with a disease or other specific characteristic of interest to the public.

5. Applicant argues that the instant nucleic acid molecules can be used as probes or a source for primers.

This is not persuasive because while the specification teaches that the claimed nucleic acid molecules "*may be employed* to obtain other nucleic acid molecules" (emphasis added), the specification does not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 7-27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that the claimed nucleic acid molecules are enabled, as stated in the utility rejection.

This is not persuasive for the reasons set forth in the Utility rejection above.,

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 18-27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that "a person of ordinary skill in the art would understand that Applicant had possession of the nucleic acid molecules that encode a maize or soybean enzyme or fragment thereof and that Applicant has described the claimed invention.

This is not persuasive, as the specification fails to provide written description for specific "structural features commonly possessed by members of the genus" of the disclosed SEQ ID NOs. The specification discloses SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753, which corresponds in some undefined way to cDNA/genomic DNA encoding plant species of protein/nucleic acid. The specification fails to describe any sequences which in fact encode the proteins recited in the instant claims. Therefore, the claims lack written description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number J04121 (11 July 1997), as it pertains to SEQ ID NO: 11. J04121 teaches a fragment of SEQ ID NO: 11 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number AF022733 (30 October 1997), as it pertains to SEQ ID NO: 446. AF022733 teaches a fragment of SEQ ID NO: 446 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number U28214 (20 March 1997), as it pertains to SEQ ID NO: 1108. U28214 teaches a fragment of SEQ ID NO: 1108 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number U64818 (15 May 1997), as it pertains to SEQ ID NO: 2644. U64818 teaches a fragment of SEQ ID NO: 2644 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number U72142 (29 August 1997), as it pertains to SEQ ID NO: 2681. U72142 teaches a fragment of SEQ ID NO: 2681 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank Accession Number E10417 (29 September 1997), as it pertains to SEQ ID NO: 2753. E10417 teaches a fragment of SEQ ID NO: 2753 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number S46215 (8 May 1993), as it pertains to SEQ ID NO: 11. S46215 teaches a fragment of SEQ ID NO: 11 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number X02400 (12 September 1993), as it pertains to SEQ ID NO: 935. X02400 teaches a fragment of SEQ ID NO: 935 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number M97476 (27 April 1993), as it pertains to SEQ ID NO: 2042. M97476 teaches a fragment of SEQ ID NO: 2042 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number S42124 (8 May 1993), as it pertains to SEQ ID NO: 2166. S42124 teaches a fragment of SEQ ID NO: 2166 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number X85327 (2 July 1996), as it pertains to SEQ ID NO: 2252. X85327 teaches a fragment of SEQ ID NO: 2252 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number U10282 (13 June 1994), as it pertains to SEQ ID NO: 2681. U10282 teaches a fragment of SEQ ID NO: 2681 and therefore anticipates claims 2 and 18-27.

Claims 2 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number Z18924 (4 December 1992), as it pertains to SEQ ID NO: 2753. Z18924 teaches a fragment of SEQ ID NO: 2753 and therefore anticipates claims 2 and 18-27.

Conclusion

No claims are allowed.

The rejection under 35 USC 112, 2nd paragraph has been withdrawn in view of Applicant's arguments.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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May 15, 2006
Lori A. Clow, Ph.D.
Art Unit 1631

Marjorie A. Moran
5/15/06

MARJORIE A. MORAN
PRIMARY EXAMINER